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EXAMINER

MITCHELL, GREGORY W

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/16/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/313,628
Filing Date: May 18, 1999
Appellant(s): HODGEN, GARY D.

Edward A. Meilman
Registration No.: 24,735
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 03, 2005.

S.00

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on January 03, 2005 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 21-33 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,133,814 Jones et al. 01-1979

Basu, J. "Antifertility Effect of Three New Clomiphene Analogues on Animals" Jap. J. Exp. Med., 29(6) (1973), 692-4.

Schane et al. "Fertility in the rhesus monkey following long-term inhibition of ovarian function with danazol" Fertil. Steril., 29(6) (1978), 692-4.

The Merck Manual of Medicinal Information, Home Edition, Berkow et al. Eds. Pocket Books, New York, 1997, 1225.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 21-33 are rejected under 35 U.S.C. 103. This rejection is set forth in a prior Office Action, mailed on July 01, 2004.

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(11) Response to Argument

Applicant argues that the 35 USC 103 rejection of claims 21-33 over Jones, Basu, Schane and the Merck Manual should not stand.

Applicant argues on page 5 of the appeal brief filed March 03, 2005 that Jones and Basu reflect the early beliefs about SERMs, namely that SERMs are useful in contraception. Applicant argues that in view of Clark and Greenblatt, however, indicate that the use of SERMs for contraception was contradicted. This argument is not persuasive. First, Clark specifically states that the differences observed for activity of SERMs in rodents (contraceptive) versus humans (induction of ovulation) "may be different to species differences; however, it is more likely to be due to the differences in treatment protocols." See page 4 of Applicant's Remarks, filed August 29, 2001. Second, it is noted that Greenblatt pre-dates the cited references by at least a decade. Accordingly, the skilled artisan would not understand Greenblatt to be a more contemporary teaching regarding SERMs than Jones and Basu. Taking Clark, Greenblatt, Jones and Basu together, the skilled artisan would have understood the art to teach SERMs as both contraceptives and ovulation inducers depending on treatment protocols. Thus, it is Examiner's position that it would have been obvious to the skilled artisan to combine SERMs with progestins for contraceptive purposes because it is generally considered *prima facie* obvious to combine compounds each of which are taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose.

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Applicant argues on page 5 of the appeal brief filed March 03, 2005 that because progestins are known to induce bleeding that "The finding that there is an amount of progestin which can be used to modulate the SERM bleeding problem is unexpected." This argument is not persuasive because it is Examiner's position that the use of SERMs as contraceptives is known in the art and the use of progestins as contraceptives is also known in the art. Accordingly, it would have been obvious to the skilled artisan to administer both SERMs and progestins concomitantly for the same purpose. Taken with the teaching of the Merck Index that oral contraceptives are known to cause bleeding, it is Examiner's position that it would have further been obvious to optimize the dosages of the SERMs and progestins in order to effectuate the minimal amount of bleeding possible.

Applicant argues on page 6 of the appeal brief filed March 03, 2005 that Examiner has presupposed that a composition is being claimed. This argument is not persuasive because Examiner has made no such presupposition. Examiner has stated that if it would have been obvious to one of ordinary skill in the art to combine two compositions known to be individually useful for the same purpose to provide a third composition for the very same purpose, it would have also been obvious to administer said third composition for said purpose. There would be no basis for finding the composition obvious if the artisan were not expected to use said composition for the same purpose.

Applicant argues on page 6 of the appeal brief filed March 03, 2005 that "any hypothetical concomitant use would be expected to exaggerate the bleeding problem."

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This argument is not persuasive because, as Examiner has explained above, the Merck Index teaches that oral contraceptives are known to cause bleeding. Accordingly, it would have been obvious to the skilled artisan to optimize the dosages of the concomitant treatment in order to minimize the bleeding side effects to any degree possible.

Applicant argues on page 6 of the appeal brief filed March 03, 2005 that Examiner is wrong to interpret the claims as a method of achieving contraception and not of ameliorating bleeding side effects of the SERM because the "claims specifically recite the use of the progestogenic agent in an amount effective to ameliorate or eliminate the bleeding side effect of the SERM." This argument is not persuasive because the claim is not directed to the effects described in the recitation regarding the bleeding side effect of the SERMs. Said recitation is utilized in the claims merely to indicate the *amount* of progestogenic agent, not an effect that must be eventuated by the claimed method.

Applicant argues on page 7 of the appeal brief filed March 03, 2005 that the argument that "bleeding is a normal side effect of oral contraceptives" is a "non-sequitur." This argument is not persuasive because the teaching is used by Examiner to show that it would have been obvious to optimize the dosages of the SERM and the progestogenic agent in order to minimize the bleeding side effect known to be caused by the administration thereof.

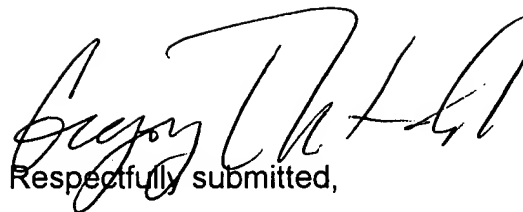
Applicant's argument that Examiner has only used the observation that "methods of contraception have been occasioned by bleeding" to provide a "reason for

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'something' to be done, [] does not provide any factual basis of what should be done, much less what is being done in the present invention." Again, it is Examiner's position that the claims are directed to a method of contraception and not a method of reducing the bleeding side effect of the contraceptives. Accordingly, it would have been obvious to the skilled artisan to (1) utilize the combination of SERMs and progestogenic agents as a contraceptive combination; and to (2) optimize the dosages thereof to minimize the known side effects of the contraceptive such that the artisan would arrive at the claimed dosage amounts (namely those wherein "the amount of the agent which exhibits progestogenic activity is effective to ameliorate or eliminate the bleeding side effects of the Selective Estrogen Receptor Modulator."). Likewise, Applicant's arguments that "The references do not teach or even suggest, either alone or in combination, an improvement in the use of the compounds or methods of ameliorating or eliminating side effects, such as uterine bleeding, that accompany any (presumptive) contraceptive use of SERMs" is not persuasive for the reasons that Examiner does not agree that Applicant is claiming a method of ameliorating or eliminating the bleeding side effects.

For the above reasons, it is believed that the rejections should be sustained.

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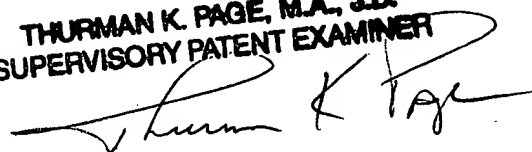
Respectfully submitted,

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Examiner
Art Unit 1617

gwm
June 9, 2005

Conferees

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